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SUPPLEMENT TO
REPORT NO.

THIS IS UNEVALUATED INFORMATION

REORGANIZATION OF DRUG PRODUCTION, AND
DISTRIBUTION AND CONTROL IN CZECHOSLOVAKIA

REORGANIZATION OF HEALTH ENTERPRISES

Article I

3. Lécive Rostliny (Medicinal Herbs) National Enterprise, in Zbraslav nad Vitavou, purchase, handles, and processes medicinal herbs, and organizes their cultivation and collection.

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		<u>DISTRIBUTION</u>					
STATE	<input checked="" type="checkbox"/>	NAVY	<input checked="" type="checkbox"/>	NSRB		DISTRIBUTION	
ARMY	<input checked="" type="checkbox"/>	AIR	<input checked="" type="checkbox"/>	FBI			

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Article II

The following enterprises have been established to replace the former Medika (Medical Supplies) National Enterprise:

1. The following enterprises prepare, handle, and issue drugs, hygienic supplies, and optical goods.

Prague Medika National Enterprise, in Prague.

Central Bohemian Medika National Enterprise, in Prague.

South Bohemian Medika National Enterprise, in Ceske Budejovice.

Plzen Medika National Enterprise, in Plzen.

Karlovy Vary Medika National Enterprise, in Karlovy Vary.

Usti Medika National Enterprise, in Usti nad Labem.

Liberec Medika National Enterprise, in Liberec.

Hradec Kralove Medika National Enterprise, in Tyniste nad Orlici.

Pardubice Medika National Enterprise, in Pardubice.

Jihlava Medika National Enterprise, in Jihlava.

Brno Medika National Enterprise, in Brno.

Olomouc Medika National Enterprise, in Prerov.

Valassko Slovak Medika National Enterprise, in Uherske Hradiste.

Ostrava Medika National Enterprise, in Ostrava.

Bratislava Medika National Enterprise, in Bratislava.

Nitra Medika National Enterprise, in Topolcany.

Banska Bystrica Medika National Enterprise, in Zvolen.

Zilina Medika National Enterprise, in Zilina.

East Slovak Medika National Enterprise, in Kosice.

2. The following enterprises handle and allot imported and other special drugs, hygienic supplies, and optical goods which have been assigned to their jurisdiction by the Ministry of Health.

Sanitas (Health) Warehouses National Enterprise, in Prague.

Sanitas Warehouses National Enterprise, in Bratislava.

3. Zdravotnicke Opravny a Laboratorni Potreby (Health Supply Repair Shops and Laboratory Needs) National Enterprise, in Prague. Repairs medical instruments and tools, maintains technical medical equipment, and supplies laboratory items.

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Article III

The property of the newly established national enterprises shall include certain property of the former national enterprises from which they were organized. The new enterprises shall also take over certain rights and obligations of the former enterprises, according to their status as of 30 March 1952, including the rights and obligations resulting from commercial agreements.

The extent of the property holdings of the new national enterprises, and the disposition of the rights and obligations which they took over, will be determined by special decisions of the Ministry of Health.

ESTABLISHMENT OF THE CZECHOSLOVAK STATE
INSTITUTE FOR DRUG CONTROL

The enterprises and establishments engaged in the production and distribution of drugs in Czechoslovakia themselves control the quality of their drugs. They have their own control institutes and laboratories for this purpose.

To control the quality of drugs according to the most recent findings of scientific research, and in order that drugs which have already been subjected to quality control in production or distribution may be rechecked if necessary, the state health administration also must control the quality of drugs, using special control equipment. So far, this function has been filled primarily by Department IV of the State Health Institute, the Drug Research Department. This institute was established by law in 1949. Experience has shown, however, that it cannot alone perform effectively all the extensive and varied tasks now assigned it.

Therefore, in accordance with the recent reorganization of public health services, the State Health Institute is establishing independent institutes for each field of public health. For the same reason, a special institute is to be established to exercise quality control of drugs: The State Institute For Drug Control.

This institute will perform technical and scientific work primarily for the state health administration, including the military health administration. Like the existing Department IV of the State Health Institute, the new institute normally will do only control work, and will perform research only when necessary for the execution of quality control. Thus its research work will consist primarily of research on control methods; actual research on drugs will be done by other institutes.

The institute's control activity will be directed primarily toward drugs which have a particularly strong effect on the human organism, and whose production requires special care to prevent contamination. These drugs include insulin, penicillin, streptomycin, and other antibiotics, as well as arsenobenzenes, sera, inoculation agents, bacterial preparations, and hormone and vitamin preparations. The institute will also devote considerable attention to drugs which have been found faulty by the state health administration, or in which faults are suspected.

In addition to drugs, the institute will also control other medical supplies: therapeutic aids such as ether for anesthesia, surgical sutures, wadding and bandaging materials, diagnostic aids, disinfectants and other preparations for the destruction of parasites, and insecticides and rodenticides.

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The control of the quality of various protective salves used by workers to protect themselves against the dangers of their work, particularly work involving heat, dust, and caustic agents, will be done under the labor-hygiene program, in special institutes for labor hygiene, physiology, and pathology, or in hygienic-epidemiological stations. Similarly, the institute will not control so-called dietetic preparations because these preparations belong to the field of food hygiene. Nor will the institute control vaccines, sera, or biological diagnostic preparations for veterinary medicine, which are produced in establishments of the Ministry of Agriculture, because the control of these drugs is done by the producing institutes and veterinary establishments themselves.

The control activity of the institute will be directed more toward controlling drugs while still in production, and toward controlling imported drugs while still in the possession of the importer, to eliminate the distribution of faulty or insufficiently effective drugs and to encourage the production of fully effective drugs. This change of emphasis is possible because the distributing enterprises are now building their own network of control laboratories in individual krajs, so that the institute's control of the distribution of drugs, particularly in pharmacies, will not have to be so extensive.

The institute will act partly on its own initiative and partly on directives of the Ministry of Health. The advice of other agencies also will be welcomed. Suggestions from workers in Department IV of the State Health Institute have already had good results.

Within its jurisdiction, the newly established institute will carry out projects for agencies other than those of the state health administration, insofar as this does not interfere with the fulfillment of its principal tasks.

The courts will be empowered to demand expert opinions from the institute, according to existing civil and penal law. Payment for expert opinions will be made on the basis of the regulations concerning payments and reimbursements granted to permanent experts and consultants.

The Ministry of Health issued the following announcement concerning the State Institute for Drug Control, on 24 April 1952:

Article I

1. The State Institute for Drug Control is hereby established in Prague, with a regional institute in Bratislava.
2. The institute is under the jurisdiction of the Ministry of Health and is an establishment of the state administration.

Article II

1. The new institute shall take over the duties and jurisdiction in the control of drugs which were previously assigned to the State Health Institute. The institute shall carry out technical and scientific control work in the field of drugs, for agencies of the state health administration. This will include especially:

- a. Control and experimentation in the physical, chemical, pharmacological and biological aspects of drug quality;
- b. Research on drug-control methods;
- c. Advanced technical training in drug control for public health workers.

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2. The institute may do scientific and technical work in the field of control of other medical supplies, particularly therapeutic and diagnostic aids and disinfectants or other agents which are used to improve hygiene and to fight communicable diseases.

Article III

1. A director shall administer the institute technically, administratively, and economically.

2. The Ministry of Health shall transfer to the institute a suitable number of technical and other employees from the State Health Institute.

3. The institute shall be responsible for its own personnel.

Article IV

The organization and operation of the institute shall be worked out in detail by the Ministry of Health.

Article V

On request, the institute may conduct technical and scientific control work for other government agencies, for socialist organizations and other legal persons, and for individuals.

Article VI

This announcement is effective as of 1 May 1952.

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